UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AMERICAN REGENT, INC., *Plaintiff*, v. SOMERSET THERAPEUTICS, LLC, SOMERSET PHARMA, LLC, ODIN PHARMACEUTICALS, LLC, APOTEX INC, APOTEX CORP, RK PHARMA, INC., and ACCORD HEALTHCARE, INC., *Defendants*.	Honorable Brian R. Martinotti, U.S.D.J. Civil Action Nos. 24 CV 1022 (BRM)(CLW) 24 CV 1030 24 CV 1169 24 CV 2268 24 CV 9600 (Consolidated)

DEFENDANTS' OPENING *MARKMAN* BRIEF

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I. INTRODUCTION

Defendants Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC (collectively, "Somerset"), RK Pharma, Inc. ("RK Pharma"), Apotex Inc. and Apotex Corp. (collectively, "Apotex"), and Accord Healthcare, Inc. ("Accord") (the foregoing collectively, "Defendants") submit this Opening Claim Construction Brief. For the reasons set forth herein, Defendants respectfully request that the Court adopt their proposed constructions of the disputed terms of the patents-in-suit,[1] which refer to the amount of the salt form of certain trace elements covered by the patents.[2] These amounts appear in the patents in adult and pediatric compositions, respectively:

- "[about] 7.41 mg of zinc sulfate or zinc sulfate heptahydrate, 0.75 mg of cupric sulfate or cupric sulfate pentahydrate, 151 mcg of manganese sulfate or manganese sulfate monohydrate"
- "[about] 2,470 mcg of zinc sulfate or zinc sulfate heptahydrate, about 150 mcg of cupric

[1] As set forth in the Joint Claim Construction and Prehearing Statement (ECF No. 110), Defendants also identified six claim terms that they contend are indefinite. *Id.* at 2. The parties agreed to defer the indefiniteness terms until "after the parties have completed fact and expert discovery" (*id.* at 3), as is routinely done in this Court. *See, e.g.*, *Fresenius Kabi USA, LLC v. Fera Pharm., LLC*, 2016 WL 5109142, at *9 (D.N.J. Sept. 20, 2016) ("Courts in this Circuit routinely decline to address indefiniteness arguments in claim construction because they are potentially dispositive, require a high burden of proof, and may more profitably be considered in connection with patent validity."); *Adapt Pharma Op. Ltd. v. Teva Pharm. USA, Inc.*, No. 16-7721(JLL), 2019 WL 1789463, at *4 (D.N.J. Apr. 24, 2019) ("It is not uncommon for courts to defer ruling on an indefiniteness challenge at the claims construction stage where such a ruling would be better suited for trial."); *see also Otsuka Pharm. Co., Ltd. v. Zenara Pharma Private Ltd.*, No. 19-1938-LPS, 2021 WL 31720172021, at *4 (D. Del. July 27, 2021) ("[I]t is most appropriate – and likely even necessary – to defer ruling on the indefiniteness dispute presented by the parties."). As such, these six claim terms will not be briefed at this stage of the case and there is a single disputed issue to be resolved at *Markman.*

[2] The disputed sulfate limitations are specifically recited in the following asserted claims: claims 15, 31–32, and 34–35 of the '548 patent; claims 12, 14–15, and 25–27 of the '022 patent; and claims 12, 14, 15, and 26–28 of the '956 patent.

sulfate or cupric sulfate pentahydrate, about 8.22 mcg of manganese sulfate or manganese sulfate monohydrate"[3]

In short, Defendants' proposed constructions are faithful to the plain and ordinary meaning of the claim language and intrinsic record, whereas Plaintiff's constructions improperly broaden the claims by rewriting them to include additional language not supported by the shared specification.

II. FACTUAL BACKGROUND

A. The Patents-in-Suit

This is a patent infringement lawsuit arising from Defendants' respective Abbreviated New Drug Applications seeking FDA approval to market generic versions of the drug products Multrys® and Tralement®, owned and marketed by Plaintiff American Regent, Inc. ("ARI" or "Plaintiff"). Multrys® and Tralement® are trace element compositions of zinc, copper, manganese, and selenium for parenteral or enteral nutrition. Tralement® contains concentrations indicated for adult and pediatric patients, and Multrys® contains concentrations indicated for pediatric and neonatal patents. Plaintiff brought suit against Defendants, alleging infringement of United States Patent Nos. 11,786,548 ("the '548 patent"), 11,975,022 ("the '022 patent"), 11,998,565 ("the '565 patent"), 12,150,956 ("the '956 patent"), and 12,150,957 ("the '957 patent") (collectively, the "Patents-in-Suit").

Each of the Patents-in-Suit shares the same specification and includes claims directed to either: (1) a trace element composition, usually injectable; or (2) a method of administering such a composition to a patient. The claimed compositions contain, among other things, elemental zinc,

[3] The patents-in-suit interchangeably use the concentration symbols "mcg" and "μg" to represent micrograms. For conversion, 1,000 mcg equals 1 mg.

copper, manganese, and selenium. The shared specification teaches that these trace elements can be obtained from salt forms (i.e., sulfates) and/or with added water (i.e., hydrates):

> the elemental zinc is obtained from zinc sulfate or zinc sulfate heptahydrate, the elemental copper is generated from cupric sulfate or cupric sulfate pentahydrate, the elemental manganese is from manganese sulfate or manganese sulfate monohydrate and the elemental selenium is obtained from selenious acid.

'548 patent at 10:44–49.

B. The Parties Dispute the Meaning of the Claimed Sulfate Limitations

The parties dispute the proper construction of the sulfate limitations. The parties' proposed constructions, as disclosed in the Joint Claim Construction and Prehearing Statement (D.I. 110), are as follows:

Claim Terms	Defendants' Proposed Construction	Plaintiff's Proposed Construction
"about 7.41 mg of zinc sulfate or zinc sulfate heptahydrate, about 0.75 mg of cupric sulfate or cupric sulfate pentahydrate, about 151 mcg of manganese sulfate or manganese sulfate monohydrate" "7.41 mg of zinc sulfate or zinc sulfate heptahydrate, 0.75 mg of cupric sulfate or cupric sulfate pentahydrate, 151 mcg of manganese sulfate or manganese sulfate monohydrate" "about 7.41 mg of zinc sulfate or zinc sulfate heptahydrate, about 0.75 mg of cupric sulfate or cupric sulfate pentahydrate, about 151 µg of manganese sulfate or manganese sulfate monohydrate"	about 7.41 mg of zinc sulfate or about 7.41 mg of zinc sulfate heptahydrate, about 0.75 mg of cupric sulfate or about 0.75 mg of cupric sulfate pentahydrate, about 151 mcg of manganese sulfate or about 151 mcg of manganese sulfate monohydrate / 7.41 mg of zinc sulfate or 7.41 mg of zinc sulfate heptahydrate, 0.75 mg of cupric sulfate or 0.75 mg of cupric sulfate pentahydrate, 151 mcg of manganese sulfate or 151 mcg of manganese sulfate monohydrate	about 7.41 mg of zinc sulfate or an amount of zinc sulfate heptahydrate providing the same amount of zinc, about 0.75 mg of cupric sulfate or an amount of cupric sulfate pentahydrate providing the same amount of copper, about 151 mcg of manganese sulfate or an amount of manganese sulfate monohydrate providing the same amount of magnesium / 7.41 mg of zinc sulfate or an amount of zinc sulfate heptahydrate providing the same amount of zinc, 0.75 mg of cupric sulfate or an amount of cupric sulfate pentahydrate providing the same amount of copper, 151

Claim Terms	Defendants' Proposed Construction	Plaintiff's Proposed Construction
		mcg of manganese sulfate or an amount of manganese sulfate monohydrate providing the same amount of manganese / about 7.41 mg of zinc sulfate or an amount of zinc sulfate heptahydrate providing the same amount of zinc, about 0.75 mg of cupric sulfate or an amount of cupric sulfate pentahydrate providing the same amount of copper, about 151 µg of manganese sulfate or an amount of manganese sulfate monohydrate providing the same amount of magnesium
"about 2,470 mcg of zinc sulfate or zinc sulfate heptahydrate, about 150 mcg of cupric sulfate or cupric sulfate pentahydrate, about 8.22 mcg of manganese sulfate or manganese sulfate monohydrate" "2,470 mcg of zinc sulfate or zinc sulfate heptahydrate, 150 mcg of cupric sulfate or cupric sulfate pentahydrate, 8.22 mcg of manganese sulfate or manganese sulfate monohydrate" "about 2,470 µg of zinc sulfate or zinc sulfate heptahydrate, about 150 µg of cupric sulfate or cupric sulfate pentahydrate, about 8.22 µg of manganese sulfate or manganese sulfate monohydrate"	about 2,470 mcg of zinc sulfate or about 2,470 mcg of zinc sulfate heptahydrate, about 150 mcg of cupric sulfate or about 150 mcg of cupric sulfate pentahydrate, about 8.22 mcg of manganese sulfate or about 8.22 mcg of manganese sulfate monohydrate / 2,470 mcg of zinc sulfate or 2,470 mcg of zinc sulfate heptahydrate, 150 mcg of cupric sulfate or 150 mcg of cupric sulfate pentahydrate, 8.22 mcg of manganese sulfate or 8.22 mcg of manganese sulfate monohydrate	about 2,470 mcg of zinc sulfate or an amount of zinc sulfate heptahydrate providing the same amount of zinc, about 150 mcg of cupric sulfate or an amount of cupric sulfate pentahydrate providing the same amount of copper, about 8.22 mcg of manganese sulfate or an amount of manganese sulfate monohydrate providing the same amount of manganese / 2,470 mcg of zinc sulfate or an amount of zinc sulfate heptahydrate providing the same amount of zinc, 150 mcg of cupric sulfate or an amount of cupric sulfate pentahydrate providing the

Claim Terms	Defendants' Proposed Construction	Plaintiff's Proposed Construction
		same amount of copper, 8.22 mcg of manganese sulfate or an amount of manganese sulfate monohydrate providing the same amount of manganese / about 2,470 µg of zinc sulfate or an amount of zinc sulfate heptahydrate providing the same amount of zinc, about 150 µg of cupric sulfate or an amount of cupric sulfate pentahydrate providing the same amount of copper, about 8.22 µg of manganese sulfate or an amount of manganese sulfate monohydrate providing the same amount of manganese

While the various claims recite different amounts and units for the various trace elements, all the claims and constituent elements in dispute have the same general structure. They each recite a numerical amount of an elemental sulfate form *or* an elemental sulfate hydrate form. The crux of the dispute thus centers on the meaning of the word "or" in the claims and can be illustrated by focusing on an exemplary element in an exemplary claim as shown below.

Claim Terms	Defendants' Proposed Construction	Plaintiff's Proposed Construction
"about 7.41 mg of zinc sulfate ***or*** zinc sulfate heptahydrate…."	"about 7.41 mg of zinc sulfate or about 7.41 mg of zinc sulfate heptahydrate…."	"about 7.41 mg of zinc sulfate or an amount of zinc sulfate heptahydrate providing the same amount of zinc…."

Defendants contend that "or" should have its customary meaning and thereby should modify both the sulfate and hydrate terms that follow the recited amount. Plaintiff, on the other hand, is advancing a construction whereby the hydrate form is construed to provide the "same amount" of the element as the sulfate form, which is ***not*** the numerical amount recited in the claim.

III. LEGAL STANDARD FOR CLAIM CONSTRUCTION

The claims of a patent define the scope of the invention. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996). The interpretation of claim language is a question of law for the court to decide. *Id.* at 391. Claims are to be interpreted in view of the intrinsic record: the claim language, the specification, and the prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (*en banc*); *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

Claim terms are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art at the time of invention. *Phillips*, 415 F.3d at 1313–14; *see also Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014). "Claim terms are generally given their plain and ordinary meanings to one of skill in the art when read in the context of the specification and prosecution history"—i.e., the intrinsic record. *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014). "There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of the claim term either in the specification or during prosecution." *Id*. "To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning and must clearly express an intent to redefine the term." *Id.* (citations omitted). Similarly, disavowal of a claim term's plain and ordinary meaning requires "a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Id*. at 1372.

Other than these two exceptions, "[t]he public notice function of a patent and its prosecution history requires that a patentee be held to what he declares during the prosecution of his patent." *Springs Window Fashions LP v. Novo Indus., L.P.*, 323 F.3d 989, 995 (Fed. Cir. 2003). "The prosecution history constitutes a public record of the patentee's representations concerning the scope and the meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the degree of lawful conduct." *Id*. (quotation omitted).

It is not the Court's responsibility to rewrite claims of an issued patent. *Allen Eng'g Corp. v. Bartell Indus.*, 299 F.3d 1336, 1349 (Fed. Cir. 2002); *see also Synchronoss Techs., Inc. v. Dropbox, Inc.*, 987 F.3d 1358 (Fed. Cir. 2021). "Where the meaning of a claim term is clear . . . [the court does] not rewrite the claim to preserve its validity." *Hill-Rom Servs. v. Stryker Corp.*, 755 F.3d 1367 (Fed. Cir. 2014); *see also Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371 (Fed. Cir. 2004) ("It is the job of the patentee, and not the court, to write patents carefully and consistently."); *Lucent Techs., Inc. v. Gateway, Inc.*, 525 F.3d 1200, 1215 (Fed. Cir. 2008) ("This court has repeatedly held that courts may not redraft claims to cure a drafting error made by the patentee").

"[I]t is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." *CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1153 (Fed. Cir. 1997) (quoting *Vitronics*, 90 F.3d at 1582). Extrinsic evidence, such as expert testimony, inventor testimony, dictionaries, and technical treatises and articles, may be used to guide claim construction only where it does not contradict the intrinsic evidence. *Vitronics*, 90 F.3d at 1584; *Phillips*, 415 F.3d at 1317 (extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language'"). In the end, a claim construction "that stays true to the claim language and most

naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Shire Dev., LLC v. Watson Pharms. Inc.*, 787 F.3d 1359, 1364 (Fed. Cir. 2015) (quoting *Phillips*, 415 F.3d at 1316).

IV. ARGUMENT

The key dispute is the operation of the word "or" in the claims. As illustrated above, the claims recite a specific amount of the elemental sulfate form *or* hydrated form of the various trace elements.[4] Defendants' proposed constructions are consistent with the intrinsic record and plain and ordinary interpretation of the claim language. For the reasons discussed below, Defendants respectfully request that the Court adopt Defendants' proposed constructions.

Claim construction starts with the language of the asserted claims. *See, e.g.*, *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) ("In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'"). Here, the claim language at issue is structured as follows: [a numeric amount] of A or B. The plain meaning of such a phrase is apparent. It means the recited amount of A or the recited amount of B. There is nothing in the claims that suggests that A and B should be given different numeric values or anything other than the single recited numeric value that precedes both A and B in the claims.

The claim language at issue here is "ordinary, simple English words whose meaning is clear and unquestionable." *Chef Am.*, 358 F.3d at 1373. And, where, as here, the ordinary meaning of the claim language is "readily apparent," claim construction involves "little more than the

[4] The arguments for each of the elements at issue (zinc, copper, and manganese) are the same. Therefore, for simplicity, Defendants will use zinc as the example.

application of the widely accepted meaning of commonly understood words." *Homeland Housewares, LLC v. Whirlpool Corp.*, 865 F.3d 1372, 1375 (Fed. Cir. 2017) (construing "predetermined" to mean "determined beforehand"). Defendants' proposed construction does just that and should be adopted.

Plaintiff's proposed construction, on the other hand, seeks to change the ordinary meaning of the claims and insert a conversion from the claimed numeric value to "an amount of [the hydrated form] providing the same amount" of the element as the sulfate form. While Plaintiff may wish that it had drafted its claims differently, the role of the court during claim construction is to "give effect to the terms chosen by the patentee." *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999); *SRAM Corp. v. AD-II Eng'g, Inc.*, 465 F.3d 1351, 1359 (Fed. Cir. 2006) ("we are powerless to rewrite the claims and must construe the language of the claim at issue based on the words used."); *Lodsys, LLC v. Brother Int'l Corp.*, No. 11-cv-90, 2013 WL 2949959, at *57 (E.D. Tex. June 14, 2013) ("[D]uring claim construction, the courts do not have the province to re-write the claims in a form that the patentee, on reflection, preferred."). To do otherwise "would unduly interfere with the function of claims in putting competitors on notice of the scope of the claimed invention." *Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 951 (Fed. Cir. 1993) (construing disputed claim term in accordance with its ordinary meaning and rejecting construction which attempted to "cure a drafting error").

Chef America is instructive. There, the claims recited a limitation of "heating the resulting batter-coated dough to a temperature in the range of about 400° F. to 850° F." *Chef Am.*, 358 F.3d at 1374. The Federal Circuit found that the claim language was clear: "They mean exactly what they say. The dough is to be heated to the specified temperature." *Id.* Thus, the court found that the claims should be construed as written, even though if the "dough is heated to a temperature

range of 400° F. to 850° F., as the claim instructs, it would be burned to a crisp." *Id.* The Federal Circuit therefore concluded, in accordance with its "settled practice," that it must "construe the claim as written, not as the patentees wish they had written it." *Id.* So too here.

Neither the specification nor the file history compels a different result. There is no lexicography or disclaimer. Rather, the specification uses "or" in its customary way. For example, the specification discloses that "the elemental zinc is obtained from zinc sulfate or zinc sulfate heptahydrate, the elemental copper is generated from cupric sulfate or cupric sulfate pentahydrate, the elemental manganese is from manganese sulfate or manganese sulfate monohydrate and the elemental selenium is obtained from selenious acid." '548 patent at 10:44–59. With respect to amounts, the specification discloses broad ranges of each element. *See, e.g.*, *id.* at 9:48–57.

The specification, like the claims, also discloses embodiments where the sulfate and hydrated forms are denoted by a single numerical amount and are separated by the conjunction "or." *See, e.g.*, *id.* at 11:1–9. Nowhere does the specification state that the amount of the sulfate or hydrate form should be determined by calculating an amount of one that is the "same as" the amount of the other.

The file history does not support Plaintiff's construction. The limitations at issue were specifically added during prosecution to overcome obviousness rejections. For example, during prosecution of U.S. Patent Application No. 17/365,695 which became the '548 patent and to which the other patents-in-suit claim priority, the applicants originally sought independent claim 65:

> 65. (Original) An injectable trace element composition comprising water, about 800 µg to about 4,000 µg of zinc, about 40 µg to about 400 µg of copper, about 4 µg to about 90 µg of selenium, and about 1 µg to about 80 µg of manganese per 1 mL of the injectable composition.

Ex. A at 5 (August 1, 2021 Prelim. Amendment Claims).[5] On July 7, 2022, the examiner issued a final rejection of the claims, including claim 65, asserting that it would have been obvious based on the prior art for a person of ordinary skill in the art to optimize the amount of each trace element disclosed in these multi-trace element solutions to arrive at the amounts recited in the claims. *See* Ex. B at 9 (July 7, 2022 Final Rejection).

In response, on October 7, 2022, the applicants amended claim 65 to recite certain iron and vitamin limitations, but did not amend the claimed ranges of trace elements:

> 65. (Currently Amended) An injectable trace element composition comprising water, about 800 µg to about 4,000 µg of zinc, about 40 µg to about 400 µg of copper, about 4 µg to about 90 µg of selenium, and about 1 µg to about 80 µg of manganese per 1 mL of the injectable composition, wherein the injectable composition contains 0 µg per 1 mL to about 10 µg per I mL of iron and the injectable composition does not contain any vitamins.

See Ex. C (Oct. 7, 2022 Claims).

The examiner issued another rejection on October 26, 2022, again rejecting, among others, claim 65 based on additional references. *See* Ex. D at 9 (Oct. 26, 2022 Non-Final Rejection). In response, the applicants further amended the claims, on April 26, 2023, to include specific concentrations of the salt forms:

> 65. (Currently Amended) An injectable trace element composition comprising water, **and as the active ingredients about 7.41 mg of zinc sulfate or zinc sulfate heptahydrate, about 0.75 mg of cupric sulfate or cupric sulfate pentahydrate, about 151 mcg of manganese sulfate or manganese sulfate monohydrate** and about 98 mcg of selenious acid ~~about 800 µg to about 4,000 µg of zinc, a-bout 40 µg to a-bout 400 µg of copper, a-bout 4 µg to a-bout 90 µg of selenium, and a-bout 1 µg to a-bout 80 µg of manganese~~ per 1 mL of the injectable composition, wherein the injectable composition contains impurities of chromium, aluminum, and iron, wherein the impurities are chromium in an amount not to exceed 1 µg, aluminum

[5] Exhibits are attached to the Declaration of James Richter, which is being filed contemporaneously herewith.

> in an amount not to exceed 6 µg, and 0 µg to about 10 µg of the iron ~~the injectable composition contains O µg per l mL to a bout 10 µg per l mL of iron does not contain any vitamins, and contains no chromium or chromium in an amount not to exceed l µg per l mL of the injectable composition and no aluminum or aluminum in an amount not to exceed 6 µg~~ per 1 mL of the injectable composition.

Ex. E at 5–6 (April 26, 2023 Amendment) (emphasis added). In doing so, the applicants explained that claim 65 was being amended "to include the specific mineral salts or acid of the elemental active ingredients." Ex. F at 12 (April 26, 2023 Applicant Remarks). In addition, the applicants added claims 86–90, reciting the same language, which became the other independent and dependent claims asserted in the '548 patent relating to the sulfate limitations. *See* Ex. E at 9. The same language is recited in the claims of the '022 and '956 patents. *See* claims 12, 14–15, and 25–27 of the '022 patent and claims 12, 14, 15, and 26–28 of the '956 patent.

In adding the limitations at issue, the applicants argued that the claimed compositions having "the unique combination of trace elements at the specific doses are new compositions not known in the cited art and are therefore not the result of routine optimization and would not have been obvious to a person of ordinary skill in the art." Ex. F at 22. In response, the examiner withdrew the rejections and allowed the claims, including amended claim 65, "in view of the amendments to the claims and Applicant's arguments." Ex. G at 3 (May 24, 2023 Notice of Allowance). Thus, the applicants amended the claims to recite "specific doses" in a specific way. The Court should not allow ARI to "rewrite its patent claims to suit its needs in this litigation." *Nike Inc. v. Wolverine World Wide, Inc.*, 43 F.3d 644, 648 (Fed. Cir. 1994). Therefore, the Court should construe the language in keeping with its plain and ordinary meaning proposed by Defendants.

V. CONCLUSION

For the foregoing reasons, Defendants respectfully request that this Court adopt

Defendants' proposed claim construction for the sulfate limitations.

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